

REMARKS

Applicants have amended the claims to more particularly define the invention taking into consideration the outstanding Official Action. Applicants have canceled claims 1-10 from the application, without prejudice or disclaimer and replaced them with claims 11-46 to more particularly define the invention. It is to be noted that in rewriting the claims, the number of carbon atoms in the fatty acid has been increased by two from the range of values in the original claims. This is because the structural formula is not present in the claims. As is evident to one of ordinary skill in the art from Applicants' specification, the designation of "n" as varying between 4 and 22 has been increased by the two carbon atoms shown in the formula on page 5 but not included in the range 4 and 22. Clearly, these two additional carbon atoms and the structural formula for the fatty acids clearly support the limitation for the fatty acid as containing from 6 to 24 carbon atoms as set forth in the new claim set.

In addition, the alternative language has been removed from the claims and proper Markush language has been used where appropriate. Applicants most respectfully submit that all of the claims now present in the application are in full compliance with 35 U.S.C. 112 and are clearly patentable over the references of record.

The provisional rejection of claims 1-10 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-10 of copending application 09/926,601 (actually 09/926,001) has been obviated by the filing therein of a Terminal Disclaimer and payment of the required fee. Accordingly, it is most respectfully requested that the provisional rejection be withdrawn.

The rejection of claim 1 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention has been carefully considered. In rewriting the claims, the term "unsaturated" has been omitted from the description of the acyl groups in the monoglyceride and fatty acid. Accordingly, it is most respectfully requested that this rejection be withdrawn.

The rejection of claim 3 under 35 U.S.C. 112, second paragraph, as being indefinite has been carefully considered. Claim has been canceled and rewritten so that the sentence concerning the saturation of the bonds in the acyl group has been omitted.

Furthermore, the claims are now more precise regarding the content of monoglyceride in the monoglyceride preparation as fully supported by Applicants' specification. Accordingly, it is most respectfully requested that this rejection be withdrawn in view of the amendments to the claims.

The rejection of claim 4 under 35 U.S.C. 112, second paragraph, has been carefully considered. The replace claim for claim 4 eliminates the term "and" leaving the claim in proper Markush language. Accordingly, it is most respectfully requested that this rejection be withdrawn.

The rejection of claim 5 for being indefinite for failing to particularly point out and distinctly claim the invention has been obviated by the amendments to the claims wherein the term "possibly soybean oil" has been eliminated. A new claim has been added wherein soybean oil is part of the adjuvant. It is most respectfully requested that the rejections under 35 USC 112 be withdrawn in view of the amendments to the claims.

The rejection of claims 1-4 and 6-9 under U.S.C. 103 as being unpatentable over Schroder in view of Svenson has been carefully considered but is most respectfully traversed.

Applicants wish to direct the Examiner's attention to the basic requirements of a *prima facie* case of obviousness as set forth in the MPEP § 2143. This section states that to establish a *prima facie* case of obviousness, three basic criteria first must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine the reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations.

The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art, not in applicant's disclosure. *In re Vaeck*, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991).

Section 2143.03 states that all claim limitations must be taught or suggested by the prior art. *In re Royka*, 490 F.2d 981, 180 USPQ 580 (CCPA 1974). "All words in a claim must be considered in judging the patentability of that claim against the prior art." *In re Wilson*, 424 F.2d 1382, 1385, 165 USPQ 494, 496 (CCPA 1970). If an

independent claim is nonobvious under 35 U.S.C. 103, then any claim depending therefrom is nonobvious. *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988).

Applicants also most respectfully direct the Examiner's attention to MPEP § 2144.08 (page 2100-114) wherein it is stated that Office personnel should consider all rebuttal argument and evidence present by applicant and the citation of *In re Soni* for error in not considering evidence presented in the specification.

The Official Action urges that it would have been *prima facie* obvious to add the monoglyceride preparation as taught by Schroder to the vaccine composition comprising active carbohydrate moieties (ACM) of Svenson.

Applicants most respectfully submit that Schroder relates to a novel adjuvant for use in vaccine compositions. The adjuvant is a mixture of a monoglyceride preparation and fatty acid. In the reference the only antigens mentioned are diphtheria toroid, influenza virus, and rotavirus.

Svenson relates to the use of a conjugate wherein an antigenically active carbohydrate moiety (ACM) is covalently coupled via a divalent bridge group to immunologically active carriers (IAC). Specific examples of ACM given in the citation are *saccharides from Salmonella, Streptococcus pneumonia and Haemophilus influenza*.

Applicants most respectfully submit that there is no mention of the possibility of obtaining a vaccine against TB. The most obvious reason being that at that time a lot of research had been ongoing for many years in order to improve the almost 100-years old BCG vaccine without any success. According, a person skilled in the art would not expect any simple solution to obtain an improved TB vaccine composition. Therefore, the present inventors did not expect any positive results when TB antigens were used in combination with either the adjuvant of Schroder and/or when used as an active components in the conjugate of Svenson. Surprisingly, the results were in both situations very promising and positive.

Thus, it is most respectfully submitted that it would not be obvious to one of ordinary skill in the art that the adjuvant together with a conjugate vaccine comprising

active carbohydrate moieties from *Mycobacterium tuberculosis* would be an effective vaccine against tuberculosis.

The problem to be addressed by the present invention may be formulated as to provide an improved TB vaccine composition. The closest prior art being the BCG vaccine already on the market. Accordingly, it is most respectfully requested that this aspect of the rejection be withdrawn.

The rejection of claim 5 under 35 U.S.C. 103 as being unpatentable over Schroder in view of Svenson as combined supra as applied to claims 1-4 and 6-9 above and in further view of Vercellone et al. and the rejection of claim 10 as being unpatentable over Schroder in view of Vercellone et al. have each been carefully considered but is most respectfully traversed.

Vercellone et al. describes production of LAM (lipooligosaccharide), i.e., a carbohydrate moiety, derived from *Mycobacterium tuberculosis* as well as its stimulation of TNF-alpha and cytokines. There is no mention of the use of LAM for the production of a vaccine against Tuberculosis neither is there any mention of the suitability of covalently linking LAM to a specific linker that also is bound to an immunoactivating carrier. Furthermore, Vercellone et al. does not describe a method for vaccinating an animal against a mycobacterium.

Applicants most respectfully submit that one of ordinary skill in the art would have no reason to combine the teachings of Schroder and/or Svenson when developing a TB vaccine as none of these documents mention a TB vaccine. Furthermore, a person skilled in the art would have no reason to combine the teachings of Schroder and/or Svenson with the teaching of Vercellone et al. as Vercellone et al. do not describe any specific vaccine absent the teaching in Applicants' specification. In re Fritch, 23 USPQ 1780, 1784 (Fed Cir. 1992) ("It is impermissible to engage in hindsight reconstruction of the claimed invention, using the applicant's structure as a template and selecting elements from references to fill the gaps.). Accordingly, it is most respectfully requested that this rejection be withdrawn.

In view of the above comments and further amendments to the claims, favorable reconsideration and allowance of all the claims now present in the application are most respectfully requested.

Respectfully submitted,

BACON & THOMAS, PLLC

By: *Richard E. Fichter*
RICHARD E. FICHTER
Registration No. 26,382

625 Slaters Lane - 4th Floor
Alexandria, Virginia 22314
Phone: (703) 683-0500
Facsimile: (703) 683-1080

REF:kdd
A01.wpd

DATE: May 22, 2002